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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,865

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EXAMINER

BALLARD, KIMBERLY

ART UNIT

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1649

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,865	<b>Applicant(s)</b> SARASA BARRIO, MANUEL	
	<b>Examiner</b> Kimberly Ballard	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

It is noted that claims 1-15 are drafted as "use" claims, which are not proper process claims under 35 U.S.C. 101 (see MPEP 2173.05(q)). In order to have compact prosecution in the instant application, Applicant is required to amend the process claims in accordance with 35 U.S.C. 101 in response to this Office action.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 5 in full, and each of claims 1-4 in part, drawn to the use of a peptide of SEQ ID NO: 1 conjugated to a protein that acts as an immunogen for the production of antibodies able to specifically recognize any of the predominant variants of the peptide beta amyloid A $\beta$ 40 and A $\beta$ 42.

Group II, claim(s) 6 and 7 in full, and each of claims 1-4 in part, drawn to the use of a peptide of SEQ ID NO: 2 or SEQ ID NO: 3 conjugated to a protein that acts as an immunogen for the production of antibodies able to specifically recognize any of the predominant variants of the peptide beta amyloid A $\beta$ 40 and A $\beta$ 42.

Group III, claim(s) 8 in full, and each of claims 1-4 in part, drawn to the use of a peptide of SEQ ID NO: 4 conjugated to a protein that acts as an immunogen for the production of antibodies able to specifically recognize any of the predominant variants of the peptide beta amyloid A $\beta$ 40 and A $\beta$ 42.

Group IV, claim(s) 12 in full, and each of claims 9-11 in part, drawn to the use of an antibody or active fragment or derivative of an antibody that specifically recognizes any of the predominant variant of the beta amyloid peptide, A $\beta$ 40 and A $\beta$ 42, wherein the antibody is obtained by immunization of mammals or birds with the peptide of SEQ ID NO: 1.

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Group V, claim(s) 13 and 14 in full, and each of claims 9-11 in part, drawn to the use of an antibody or active fragment or derivative of an antibody that specifically recognizes any of the predominant variant of the beta amyloid peptide, A $\beta$ 40 and A $\beta$ 42, wherein the antibody is obtained by immunization of mammals or birds with the peptide of SEQ ID NO: 2 or SEQ ID NO: 3.

Group VI, claim(s) 15 in full, and each of claims 9-11 in part, drawn to the use of an antibody or active fragment or derivative of an antibody that specifically recognizes any of the predominant variant of the beta amyloid peptide, A $\beta$ 40 and A $\beta$ 42, wherein the antibody is obtained by immunization of mammals or birds with the peptide of SEQ ID NO: 4.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-VI appears to be that they all relate to a peptide conjugate comprising various peptide fragments of amyloid- $\beta$  conjugated to a protein carrier. However, WO 99/27944 by ATHENA NEUROSCIENCES (published June 10, 1999; listed on IDS) teaches the use of compositions comprising A $\beta$  or an active fragment linked to a conjugate molecule that promotes delivery of A $\beta$  to the bloodstream of a patient and/or promotes an immune response against A $\beta$  (see paragraph spanning pp. 4-5). The WO document also discloses the production and use of an anti-A $\beta$  antibody such as for the manufacture of a medicament for prevention or treatment of Alzheimer's disease (see p. 5, lines 17-20). In particular, the A $\beta$  peptides for use in the disclosure include fragments which comprise the instantly recited sequences of SEQ ID NO: 1-4. Non-limiting examples of A $\beta$  peptides for use as conjugated immunogens include A $\beta$ 1-12, 13-28, 17-28, 25-35, 35-40, and 35-42. However, the reference generically discloses active fragment of A $\beta$  that contain an epitope, wherein the immunogenic fragments of A $\beta$  typically have a sequence of at least

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3, 5, 6, 10 or 20 contiguous amino acids from the natural peptide (see page 15, lines 1-8). Thus, the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 9 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard  
Art Unit 1649

/Elizabeth C. Kemmerer/  
Elizabeth C. Kemmerer, Ph.D.  
Primary Examiner, Art Unit 1646